

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

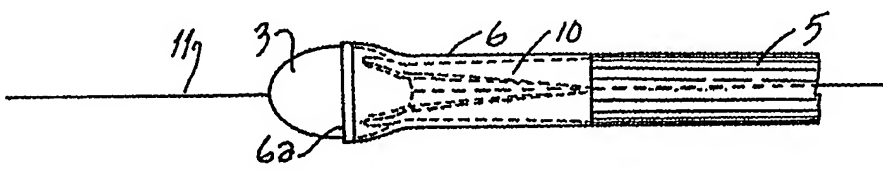
- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

PCTWORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61M 25/00, A61B 17/22	A2	(11) International Publication Number: WO 00/44428 (43) International Publication Date: 3 August 2000 (03.08.00)
(21) International Application Number: PCT/IE00/00011 (22) International Filing Date: 28 January 2000 (28.01.00) (30) Priority Data: 990058 28 January 1999 (28.01.99) IE (71) Applicant (for all designated States except US): ADAM SPENCE EUROPE LIMITED [IE/IE]; 1 Earlsfort Centre, Hatch Street, Dublin 2 (IE). (72) Inventors; and (75) Inventors/Applicants (for US only): MULHOLLAND, Patrick [IE/IE]; Ladestown, Mullingar, County Westmeath (IE). O'CARROLL, Gerard [IE/IE]; Castlebaldwin, County Sligo (IE). CONLON, Dominic [IE/IE]; Geevagh, County Sligo (IE). (74) Agents: O'BRIEN, John, A. et al.; John A O'Brien & Associates, Duncairn House, 3rd floor, 14 Carysfort Avenue, Blackrock, County Dublin (IE).		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>
(54) Title: CATHETER WITH AN EXPANDABLE END PORTION  (57) Abstract A catheter (2) is used in medical applications, for example for the retrieval of a sample from a patient or the insertion or retrieval of medical devices such as filters, stents (3) to and from the patient. The catheter (2) includes an expandable tip (6) at a leading portion of a catheter tube portion (5). This expandable tip (6) can retrieve or deliver samples, medical devices, etc. (3), which are slightly larger than the dimensions of a main catheter tube (5) inserted into the patient. The expandable tip (6) can also include extension members (10) which provide axial support to the expandable tip (6) but which still allow expansion in the radial direction.		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

- 1 -

CATHETER WITH AN EXPANDABLE END PORTIONBackground of the Invention5 Field of the Invention

The present invention is directed to a catheter, for example a retrieval or delivery catheter used in medical applications, which has an expandable end portion.

10 Discussion of the Background

Catheters are well known medical devices used to facilitate various medical procedures, such as diagnostic or delivery procedures. Catheter tubes are inserted into a body of a patient for various medical procedures. For example, a catheter
15 may be used in performing diagnostic procedures such as removing a sample from a body site of a patient. The catheter tube is used in this situation as the delivery vehicle for the medical instrument which removes the sample. Further, sophisticated medical implant devices, such as filters and stents, can be delivered and retrieved into and from the body site of the patient using a catheter.

20

Generally, a catheter has a tube portion which is relatively stiff in both axial and radial directions to allow proper placement of the catheter in the patient's body, but which may be fitted with a distal soft tip which first contacts tissues in the patient. The soft tip is provided to minimise discomfort for the patient when the
25 catheter is inserted into the patient. For example, WO-A-9808562 A describes a catheter with an insert moulded catheter tip. However, there are constraints on the use of such catheters in that such catheters can only be relatively small sized, and thus can only be used to retrieve and deliver relatively small samples and medical devices.

30

- 2 -

Summary of the Invention

Accordingly, one object of the present invention is to provide a novel catheter which can be used to retrieve larger objects and deliver and retrieve larger medical devices than in the background art.

A further object of the present invention is to provide a novel catheter which can accommodate an article with a slightly larger dimension than that of a main catheter tube itself.

The novel catheter of the present invention achieves these and other objects by including a portion near a distal tip end which is expandable in size in a radial direction to accommodate larger size samples or medical devices. The catheter includes reinforcement means to enhance the axial strength of the tip while facilitating radial expansion of the tip to accommodate an article.

As a further feature, the novel catheter of the present invention can further include reinforcing portions in the expandable portion to enhance strength in the axial direction, while still allowing expansion in the radial direction.

Most preferably the tip is a soft tip of flexible material.

In a preferred embodiment the reinforcement means comprises an extension means extending from the catheter tube portion. Preferably the tip includes a free distal end and the extension means terminates at a position that is axially spaced back from the free end of the tip.

In one embodiment of the invention the extension means comprises at least one extension member extending from said catheter tube portion into said expandable tip.

- 3 -

Preferably the extension means comprises a plurality of extension members extending from said catheter tube portion into said expandable tip. To provide a gradual change in the axial reinforcement preferably said at least one extension member is tapered toward a leading portion of said expandable tip.

5

Axial reinforcement and radial expansion is facilitated particularly when said plurality of extension members are equi-spaced in the direction of said expandable member.

10 Preferably said plurality of extension members are tapered toward a leading portion of said expandable member.

For ease of manufacture while providing the desired reinforcement characteristics preferably the number of said plurality of extension members is four.

15

To provide atraumatic transition to the soft tip preferably said at least one extension member includes a radiused tip. Ideally, said plurality of extension members each include a radiused tip.

20 In addition, for ease of passage of an article into or out of the tip preferably the tip has a free end which is rounded.

In a preferred embodiment the tip has a free end which is rounded for ease of passage of the tip through a body passageway such as the vasculature.

25

Preferably the tip comprises a tubular sleeve of flexible material. For ease of manufacture and to provide a smooth transition preferably the sleeve is attached to the catheter tube portion by heating.

- 4 -

Ideally to provide a smooth transition the tip has an outer diameter which is approximately the same dimension as the outer diameter of the catheter tube portion.

5 In one aspect the invention provides a retrieval catheter for retrieving an article such as a filter comprising a catheter tube portion and a tip extending axially from the catheter tube portion, the tip being flexible relative to the catheter tube portion, characterised in that the catheter includes reinforcement means to enhance the axial strength of the tip while facilitating radial expansion of the tip to
10 accommodate an article in the tip. Usually the article to be retrieved has a larger dimension than that of the normal internal dimension of the tip.

In one embodiment of the invention the tip is movable from a delivery configuration in which the outer diameter of the tip is approximately of the same
15 dimension as the outer diameter of the catheter portion to which it is attached, to an expandable position as an article is received in the tip.

For ease of use, preferably the tip is progressively movable to the expanded position in response to receiving an article in the tip.

20 The invention also provides a catheter tube portion having a tip extending axially from the catheter tube portion, in which the catheter tube portion includes reinforcement means to enhance the axial strength of the tip while facilitating radial expansion of the tip to accommodate an article in the tip.

25

Brief Description of the Drawings

The invention will be more clearly understood by reference to the following detailed description when considered in conjunction with the accompanying
30 drawings, wherein:

- 5 -

Fig. 1 is an overall view of the novel catheter of the present invention used with an introducer;

Fig. 2 shows a more detailed view of a tip portion of the catheter of Fig. 1;

5

Fig. 3(a) and 3(b) are cross sectional views of the tip portion of the catheter on the lines IIIa-IIIa and IIIb-IIIb respectively of Fig. 2;

10

Fig. 4(a) is an exploded view of the tip portion of the catheter of the present invention;

Fig. 4(b) is a cross sectional view on an enlarged scale of a distal end of the tip portion of the catheter;

15

Figs. 5(a) to 5(d) are diagrammatic views showing one operation of the catheter; and

Fig. 6 is a scale drawing, as an example, of an actual implementation of the novel catheter of the present invention.

20

Description of the Preferred Embodiments

Referring to the drawings, wherein like reference numerals designate identical or corresponding parts throughout the several views, and more particularly to Fig. 1 thereof, the overall device 1 is an introducer, e.g. a percutaneous introducer, with a catheter portion 2. Fig. 1 illustrates the catheter portion 2 according to the present invention, for example a retrieval catheter, which is attached to an introducer having a hub portion 20 and a side lead tube 21 which leads into the hub portion 20. A medical instrument to be inserted into a patient is placed through the hub portion 20. This medical instrument placed through the hub portion 20 may be, as examples, a retrieval element to retrieve a sample, a clot or

25

30

- 6 -

previously inserted medical device such as a stent or filter from a patient's body, or a delivery element to deliver a medical device to a patient's body.

5 The catheter 2 may also be used to deliver or retrieve another catheter. The catheter portion 2 of Fig. 1 includes a catheter tube portion 5 which is relatively rigid in both the axial and radial directions to facilitate delivery of the catheter tube portion 5 through a lumen. That is, the catheter tube portion 5 is a portion actually inserted into the patient.

10 The catheter portion 2 of the present invention further includes an expandable soft tip portion 6 with a distal tip area 6a. The expandable tip 6 is in the form of a sleeve which has an outer diameter which is nominally the same as the outer diameter of the catheter tube portion 5. The distal soft tip area 6a initially
15 contacts tissues of the patient as the catheter tube portion 5 is inserted into the patient, and minimises discomfort in the patient by virtue of its softness. The expandable soft tip portion 6 is flexible in both the axial and radial directions, and particularly is expandable in the radial direction. This expandable tip portion 6 may be made of a radiopaque or non-radiopaque material. Examples of materials for the expandable tip portion 6 include PEBA (polyether block polyamide),
20 nylon, polyurethane or polyethylene.

Figs. 2, 3 and 4 provide further details of the catheter portion 2 including the expandable soft portion 6. The catheter portion 2 includes extension legs 10 formed inside of the expandable portion 6. That is, the catheter tube portion 5 is
25 processed to form extension legs 10 at the leading edge of the catheter tube portion 5. The extension legs 10 can be formed in the catheter tube portion 5 by, for example, cutting catheter tube portion 5 using a punch and die set with a profile to achieve a desired taper in the extension legs 10. The extension legs 10 provide a reinforcement in the axial direction of the expandable portion 6 over
30 their length to enhance the strength of expandable portion 6 in the axial direction, while still providing expansion in the radial direction. In the embodiment shown

- 7 -

in Figs. 2-4 four extension legs 10 are equi-spaced around the expandable portion 6 to provide support in the axial direction and uniform flexibility in the radial direction. These extension legs 10 are tapered towards the free end of the expandable portion 6 to provide a gradually increasing controlled axial flexibility to allow the catheter tube portion 5 to be comfortably guided into the patient.

The expandable portion 6, which as noted above can be formed of a radiopaque or non-radiopaque material such as PEBA, nylon, polyurethane or polyethylene, can be secured to the main catheter tube portion 5 by heating such as by RF (radio frequency) welding the expandable portion 6 to the main catheter tube portion 5. On heating, the extension legs 10 merge into the expandable portion 6.

It will be noted that the expandable soft portion 6 extends distally beyond the axial extent of the extension legs 10 to provide the distal soft tip 6a which is not axially reinforced. The soft tip 6a has a free end that is rounded internally at 23 for ease of passage of an article 3, and is also rounded externally at 24 for ease of atraumatic passage of the tip through a body passageway such as the vasculature.

Fig. 6 shows an actual implementation of the catheter portion 2 in the present invention. Element 12 shows distal tips of the extension legs 10, and element 13 shows proximal tips of the extension legs 10, which tips 12, 13 can be radiused. That is, the tips 12, 13 of the extension legs 10 can be rounded to prevent creating a sharp edge, and thereby generating a weak point in the soft tip area 6a or the expandable portion 6. Generating a weak point in the expandable portion 6 could result in a tear in the soft tip, and if the tips 12, 13 of the extension legs 10 are radiused such a weak point and resulting tear may be prevented. Typical dimensions in millimetres are as follows:

	l_1	:	18.00 ± 1.50
30	l_2	:	15.00 ± 0.25
	l_3	:	0.70

- 8 -

Internal d : 2.03 ± 0.04
Tip radius : R 0.15 @ 90° intervals

5 Figs. 5(a) to 5 (d) show the catheter 2 of the present invention in use as a retrieval catheter as an example of one use of catheter 2. As shown in Fig. 5(a), an article 3 for retrieval, for example a sample or clot within a patient or a medical device such as a stent or filter previously inserted in the patient, is approached by the catheter tube portion 5. A retrieval device may be inserted in the introducer 1 and through the hub 20, through the catheter tube portion 5, and then through the expandable portion 6, to contact the sample 3. Alternatively the article 3, especially when in the form of a medical device such as a filter, may be attached, on introduction, to a guide wire 11 as shown in Fig. 5(a). Th retrieval device then retrieves the article 3 into the expandable portion 6 of the catheter portion 2 as shown in Figs. 5(b) to 5(d). The article 3 is first pulled back by pulling the guide wire and engages the distal tip 6a which is not reinforced and expands radially to receive the proximal end of the article 3. As the article 3 is drawn further back into the expandable portion 6 the expandable portion 6 expands radially outwardly. However the expandable portion 6 is gradually axially reinforced by the extension legs 10 to smooth the capture of the article 3. This expandable portion 6 extending axially from the catheter tube portion 5 is flexible relative to the catheter tube portion 5. The catheter portion includes reinforcement means to enhance the axial strength of the expandable portion 6 while facilitating radial expansion of the tip to accommodate an article 3 in the expandable portion 6. The tip expands to accommodate the article 3. As noted above, the extension legs 10 provide some support in the axial direction, but still allow expansion in the radial direction, to thereby allow expandable portion 6 to expand to allow the article 3 to be drawn into the expandable portion 6. The catheter tube portion 5 can then be removed from the patient with the article 3 housed therein.

30 In this way, this operation in the present invention allows a sample or device 3 which may be larger than the catheter tube portion 5 to be retrieved from a

- 9 -

patient. A medical device which may be larger than the catheter tube portion 5 can also be delivered to a patient in a similar manner.

5 Obviously, numerous modifications and variations of the present invention are possible in light of the above teachings. It is therefore to be understood that within the scope of the appended claims the present invention may be practised otherwise than as specifically disclosed therein.

- 10 -

CLAIMS

1. A catheter comprising a catheter tube portion and a tip extending axially from the catheter tube portion, the tip being flexible relative to the catheter tube portion, characterised in that the catheter includes reinforcement means to enhance the axial strength of the tip while facilitating radial expansion of the tip to accommodate an article in the tip.
5
2. A catheter as claimed in claim 1 wherein the tip is a soft tip of flexible material.
10
3. A catheter as claimed in claim 1 or 2 wherein the reinforcement means comprises an extension means extending from the catheter tube portion.
4. A catheter as claimed in claim 3 wherein the tip includes a free distal end and the extension means terminates at a position that is axially spaced back from the free end of the tip.
15
5. A catheter as claimed in claim 3 or 4 wherein the extension means comprises at least one extension member extending from said catheter tube portion into said expandable tip.
20
6. A catheter as claimed in any of claims 3 to 5 wherein the extension means comprises a plurality of extension members extending from said catheter tube portion into said expandable tip.
25
7. A catheter as claimed in claim 6 wherein said at least one extension member is tapered toward a leading portion of said expandable tip.
8. A catheter as claimed in claim 6 or 7 wherein said plurality of extension members are equi-spaced in the direction of said expandable tip.
30

- 11 -

- 5
9. A catheter as claimed in any of claims 6 to 8 wherein said plurality of extension members are tapered toward a leading portion of said expandable tip.
10. A catheter as claimed in any of claims 6 to 9 wherein the number of said plurality of extension members is four.
- 10 11. A catheter as claimed in any of claims 6 to 10 wherein said at least one extension member includes a radiused tip.
12. A catheter as claimed in claim 9 wherein said plurality of extension members each include a radiused tip.
- 15 13. A catheter as claimed in any preceding claim wherein the tip has a free end which is rounded for ease of passage of an article.
14. A catheter as claimed in any preceding claim wherein the tip has a free end which is rounded for ease of passage of the tip through the vasculature.
- 20 15. A catheter as claimed in any preceding claim wherein the tip comprises a tubular sleeve of flexible material.
- 25 16. A catheter as claimed in claim 15 wherein the sleeve is attached to the catheter tube portion by heating.
17. A catheter as claimed in any preceding claim wherein the tip has an outer diameter which is approximately the same dimension as the outer diameter of the catheter tube portion.
- 30

- 12 -

18. A retrieval catheter for retrieving an article comprising a catheter tube portion and a tip extending axially from the catheter tube portion, the tip being flexible relative to the catheter tube portion, characterised in that the catheter includes reinforcement means to enhance the axial strength of the tip while facilitating radial expansion of the tip to accommodate an article in the tip.
19. A retrieval catheter as claimed in claim 18 wherein the article to be retrieved has a larger dimension than that of the normal internal dimension of the tip.
20. A catheter as claimed in any preceding claim wherein the tip is movable from a delivery configuration in which the outer diameter of the tip is approximately of the same dimension as the outer diameter of the catheter portion to which it is attached, to an expandable position as an article is received in the tip.
21. A catheter as claimed in any preceding claim wherein the tip is progressively movable to an expanded position in response to receiving an article in the tip.
22. A catheter tube portion having a tip extending axially from the catheter tube portion, characterised in that the catheter tube portion includes reinforcement means to enhance the axial strength of the tip while facilitating radial expansion of the tip to accommodate an article in the tip.

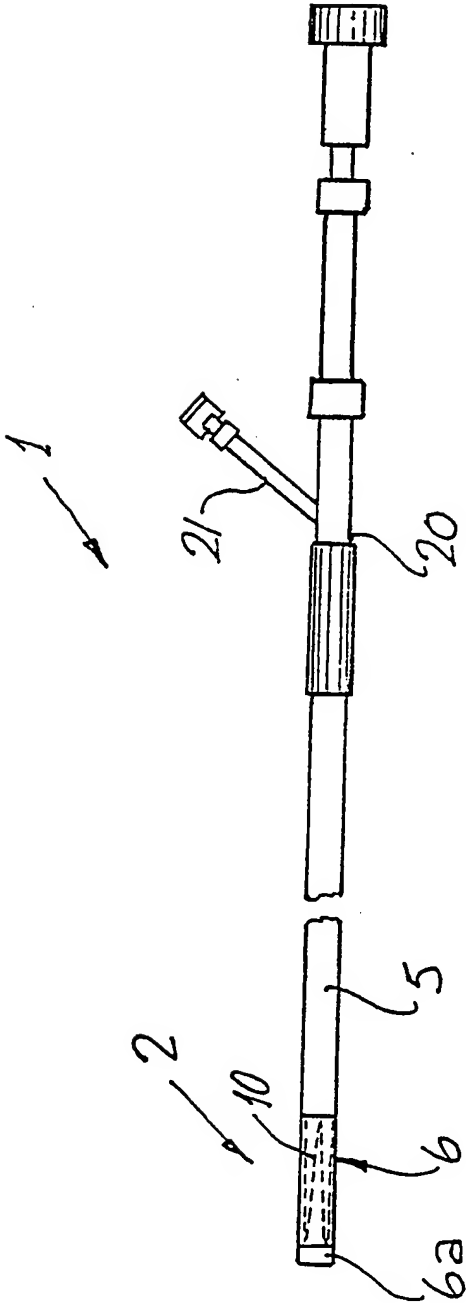


Fig.1

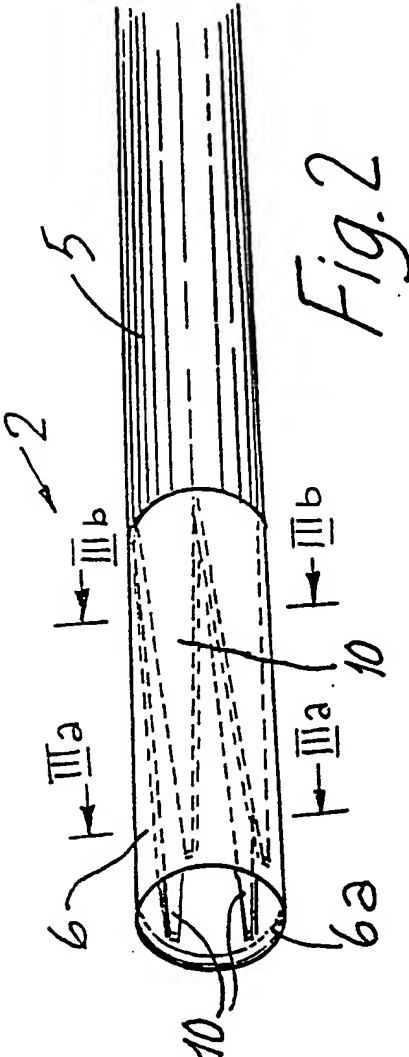


Fig. 2

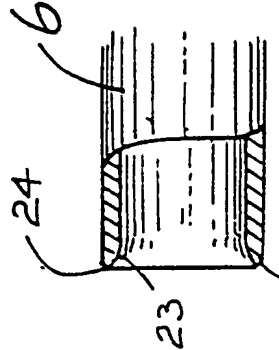


Fig. 4(b)

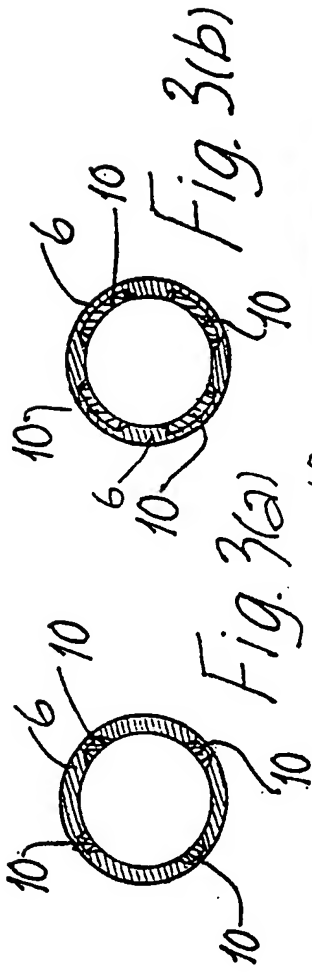


Fig. 3(a)

Fig. 3(b)

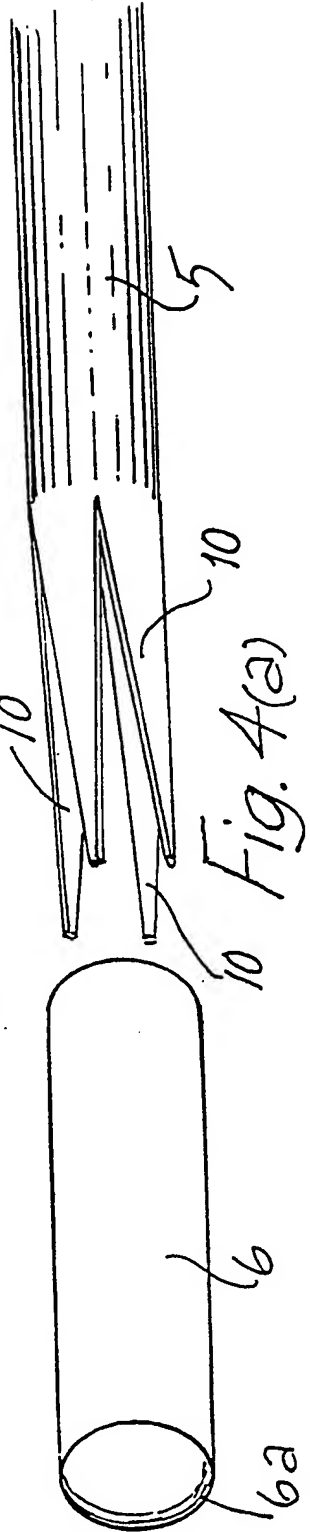
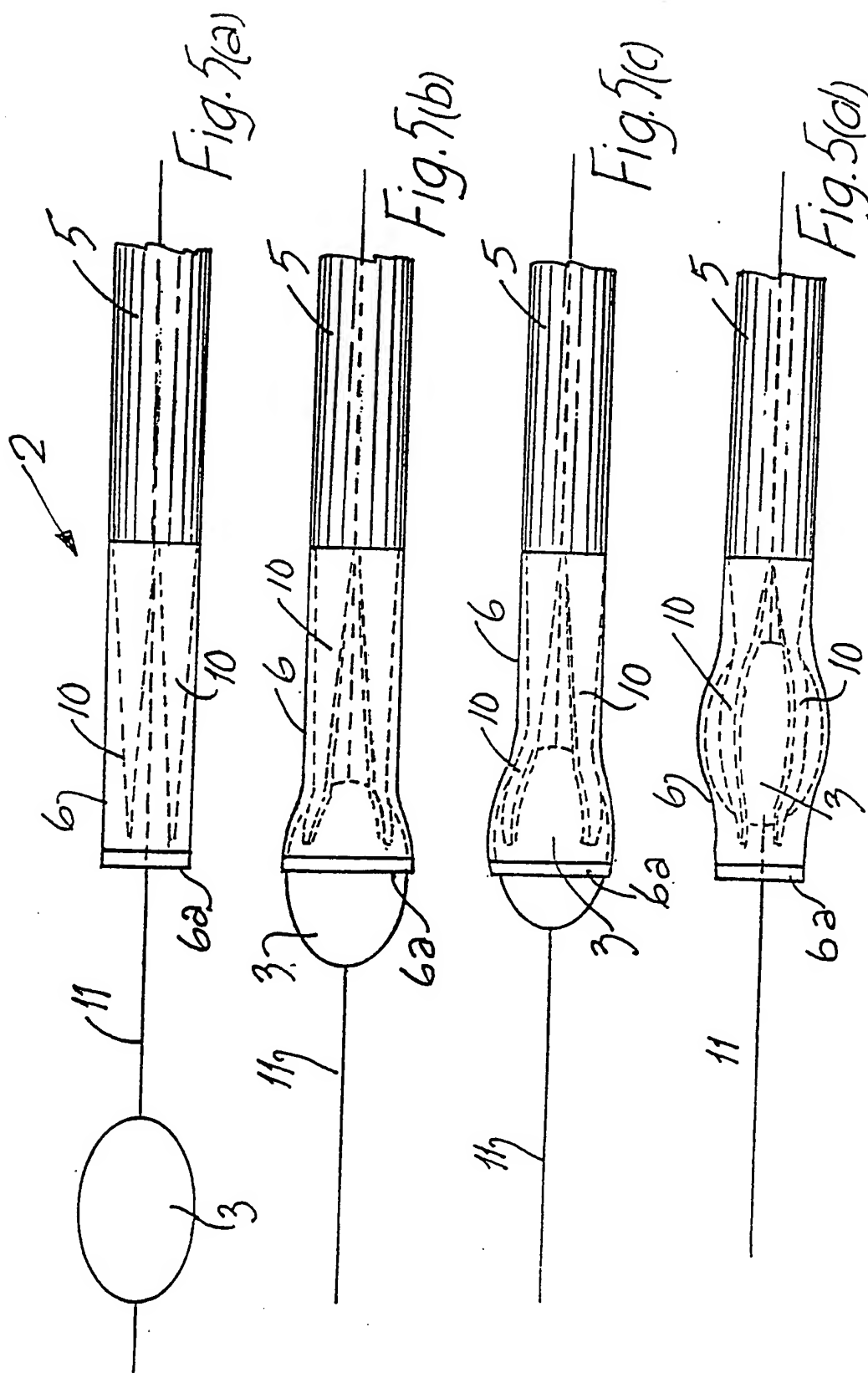


Fig. 4(a)



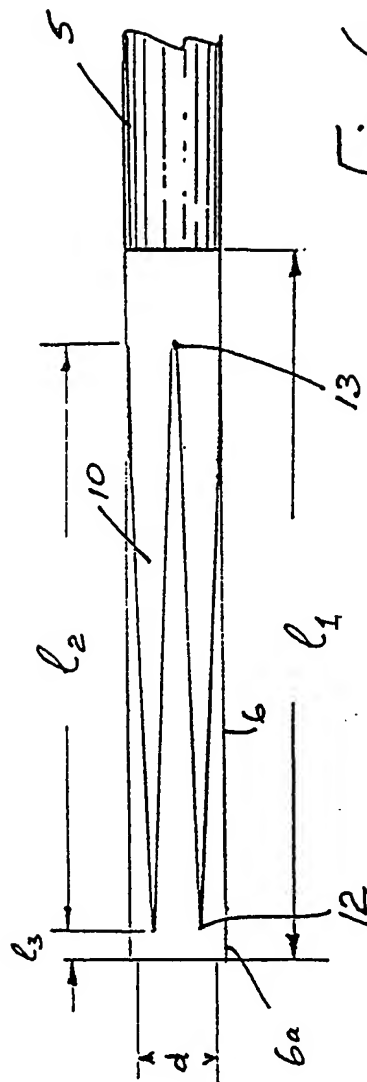


Fig. 6

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IE 00/00011

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/00 A61B17/22

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 707 359 A (BUFALINI) 13 January 1998 (1998-01-13) abstract; figures 1-8 ---	1-22
A	US 5 312 417 A (WILK) 17 May 1994 (1994-05-17) abstract; figures 1-6 ---	1-22
A	US 4 611 594 A (GRAYHACK ET AL.) 16 September 1986 (1986-09-16) abstract; figures 1-9 ---	1-22
A	EP 0 743 046 A (CORDIS EUROPE) 20 November 1996 (1996-11-20) abstract; figures 1-5 ---	1-22
	--- -/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document relating to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"Z" document member of the same patent family

Date of the actual completion of the international search

12 April 2000

Date of mailing of the international search report

19/04/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5618 Patentlaan 2
NL - 2280 MV Rijswijk
Tel. (+31-70) 340-2040; Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Michels, N

INTERNATIONAL SEARCH REPORT

International Application No.

PCT/IE 00/00011

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 102 415 A (GUENTHER ET AL.) 7 April 1992 (1992-04-07) abstract; figures 1-6 -----	1-22

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IE 00/00011

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 5707359	A	13-01-1998	NONE	
US 5312417	A	17-05-1994	NONE	
US 4611594	A	16-09-1986	NONE	
EP 0743046	A	20-11-1996	NL 1000400 C NL 1001410 C	20-11-1996 20-11-1996
US 5102415	A	07-04-1992	DE 8910603 U CH 682978 A	07-12-1989 31-12-1993